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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/117,810	05/12/99	SCHUTZ G	012627-007

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EXAMINER	
LU,F	
ART UNIT	**PAPER NUMBER**
1655	8

DATE MAILED: 08/10/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/117,810	Schutz et al.,
Examiner	**Group Art Unit**
Frank Lu	1655

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-4 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-4 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 7

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Location of Application

1. The Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1655.

Claim Objections

2. Claim 1 and 2 are objected to because of the following informalities: Note that "CREM", "TP-1", and "MCS" are abbreviations. They can only be used after each phrase appears once.

3. Claim 4 is objected to because of the following informalities: "claim 5" on line 1 should be "claim 3".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: how to investigate and monitor spermatogenesis.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Delmas *et al.*, (Mol. Endocrinol. 7, 1502-1514, November 1993).

Delmas *et al.* teach induction of cAMP-responsive element modulator (CREM) activator proteins in spermatids and their down-stream targets. They showed that CREM tau was efficiently phosphorylated at a serine residue at position 117 by the protein kinase-A endogenous to germ cells. This indicated that CREM tau constitutes a natural target of the adenylyl cyclase pathway during spermatogenesis. The phosphorylated CREM tau became a powerful activator. The rise in CREM tau protein coincided with the transcriptional activation of several genes such

as the male germ cell-specific RT7. The RT7 promoter was shown to be cAMP inducible and activated by CREM tau in transfection assays (page 1502, abstract). Using Western and Northern analysis, they further showed that R7 RNA appeared on exactly the same day as CREM proteins were first produced. As a control, the same Northern blot was hybridized with an actin probe to show that comparable amounts of RNA were loaded in each lane (as a standard reagent). These experiments revealed a good correlation between CREM protein synthesis and RT7 transcription activation (first paragraph of left column in page 1509 and Figure 6). In cotransfection experiments, CREMτ expression vector and a reporter chloramphenicol acetyl transferase (CAT) vector containing the RT7 promoter cAMP-responsive element (CRE) were cotransfected into human choriocarcinoma JEG-3 cells. Coexpression of CREMτ enhanced activation of the RT7 CRE by cAMP. Thus the RT7 CRE is functional and potentially represents a cellular target of CREM transregulatory function (second paragraph of left column in page 1509 and Figure 7 in page 1510). Note that CREM-specific antibodies blocked RT7 *in vitro* transcription (page 1502, abstract). This prior art meets the limitations of the claims.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Delmas *et al.*, (Mol. Endocrinol. 7, 1502-1514, November 1993) in view of Stratagene Catalog (1988, page 39) and in view of Foulke *et al.*, (Nature 355, 80-84, January 1992).

The teachings Delmas *et al.*, of have been summarized previously, *supra.* The teachings cover claims 1 and 2, and most of claims 3 and 4.

Delmas *et al.* do not disclose primers for amplifying DNA coding for CREM and/or CREM-dependent proteins and kit concept.

The Stratagene catalog (page 39) discloses the general concept of kits for performing gene characterization assays and discloses the advantages of kits. The kit format is utilized not only assemble a variety of different reagents together but ensure the quality and compatibility of the reagents.

Stratagene catalog (page 39) does not disclose a process for investigating and monitoring spermatogenesis and the process related kit.

Foulke *et al.* teach development switch of CREM function during spermatogenesis from antagonist to activator. RT-PCRs were used to identify and clone new CREMτ isoform (left column of page 81 and Figure 1C).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have investigated and monitored a process of spermatogenesis by determining the regulation of CREM and/or CREM-dependent protein such as RT7 using different methods including PCR and antibody-related methods as suggested by Delmas *et al et al.* and Foulke *et al.* and have organized these methods into a kit. The Stratagene Catalog 1988 would have motivated one having ordinary skill in the art to assemble reagent (s) of the methods described by Delmas *et al et al.* and Foulke *et al.* into a kit as described in claims 3 and 4. One having ordinary skill in the art at the time the invention was made would have been a reasonable expectation of success to combine these prior arts together because all of these prior arts are known and are easy to use.

Conclusion

10. No claim is allowed.

11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official

Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank L., Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
August 3, 2000

B. L. Sisson

BRADLEY L. SISSON
PRIMARY EXAMINER
GROUP ~~1800~~ 1650

8/8/00